

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: OHIO EXECUTION
PROTOCOL LITIGATION**

**This document relates to:
PLAINTIFF HENNESS**

**Execution scheduled for:
February 13, 2019**

Case No. 2:11-cv-1016

**CHIEF JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Michael R. Merz**

DEATH PENALTY CASE

Motion in Limine to Exclude Testimony of Daniel Buffington

INTRODUCTION

For the third time in this case, Defendants have identified Daniel E. Buffington as an expert they intend to call at the upcoming preliminary injunction hearing. (ECF No. 1975, PageID 88065). In his report (ECF No. 1985), Dr.¹ Buffington opines on the pharmacological properties of midazolam, induction of anesthesia, and several other matters that go beyond pharmacy. Dr. Buffington should be precluded from providing any expert opinions on these matters because he does not meet the requirements of Federal Rule of Evidence 702—he is not qualified to testify on these subject by knowledge, skill, experience, training, or education. Moreover, Dr. Buffington faces serious credibility issues because of his reputation for untruthfulness. New information obtained by Henness shows that Dr. Buffington made false and misleading statements to federal agencies and courts.

¹ Henness's use of the title of "Dr." throughout this motion should not be construed as a concession that such usage is appropriate.

TABLE OF CONTENTS

INTRODUCTION.....	i
TABLE OF CONTENTS	ii
APPLICABLE STANDARD	1
ARGUMENT	2
I. New information obtained by Henness shows that Dr. Buffington made false statements to the IRS.	3
II. Under the <i>Daubert</i> standard, Dr. Buffington cannot be qualified as an expert in pharmacology, anesthesiology, the practice of medicine, or midazolam because he has no research experience specific to midazolam and he lacks training and experience in the fields of pharmacology or anesthesiology or general medicine.....	9
A. Dr. Buffington has not done any research related to any of the drugs at issue in this case; has not authored any publications in relevant areas; and has not induced general anesthesia or installed a nasogastric tube.	10
B. Dr. Buffington’s description of his clinical experience with midazolam appears either illegal, fictional, or overstated.	11
1. Dr. Buffington’s testimony on prescribing and administering midazolam changes, even within the course of a single deposition.	11
2. Dr. Buffington was unable to produce any evidence that he actually prescribed and administered midazolam.....	12
C. Dr. Buffington lacks education and training in pharmacology, anesthesiology, or consciousness.....	15
D. Dr. Buffington’s work and teaching experience do not qualify him as an expert in this case.	17
1. “American Institute of Pharmaceutical Sciences, Inc” does not do pharmaceutical research.....	18
2. Dr. Buffington is not qualified on the basis of his involvement with professional organizations.	19
3. Including the word “pharmacology” in the name of his business does not make Dr. Buffington an expert in	

pharmacology or any other subject matter beyond pharmacy.....	21
4. Dr. Buffington’s teaching experience does not provide for a sufficient link to pharmacology, anesthesiology, or any other subject matter beyond pharmacy.....	22
E. Dr. Buffington tends to overstate his level of involvement and practical experience.	23
F. Conclusion	24
III. Opinions outside of a pharmacist’s area of competence must be excluded.	24
A. Courts exclude the testimony of pharmacists when they attempt to render an opinion outside of their area of expertise.	25
B. Dr. Buffington’s opinions outside of the area of his expertise (pharmacy) should be struck from his expert report and any associated testimony excluded.	27
1. Opinions about pharmacology should struck and associated testimony excluded.....	28
2. Opinions about pulmonary edema should be struck and associated testimony excluded.....	29
3. Opinions that amount to legal fact-finding or that touch on medical-aid-in-dying subject matter should be struck and associated testimony excluded.....	30
4. Opinions regarding the insertion of a nasogastric or orogastric tube should be struck and excluded.	30
IV. ANY expert testimony from Dr. Buffington should be excluded because he failed to provide the required disclosures under Rule 26(a).	31
CONCLUSION	32
Certificate of Service.....	34

APPLICABLE STANDARD

Federal Rule of Evidence 702 provides that “[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.”

The Supreme Court has made clear that Rule 702 imposes a “gatekeeping role” on district courts to prevent the introduction of purported expert testimony that is insufficiently reliable. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589, 597 (1993). The objective of this “gatekeeping requirement” is to “make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co. Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). As the Sixth Circuit noted, “[t]he issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question.” *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994). Allowing testimony beyond the scope of an expert’s expertise is grounds for reversal on appeal. *Id.* at 1355; *see also Wheeling Pittsburgh Steel Corp. v. Beelman River*

Terminals, Inc., 254 F.3d 706, 715 (8th Cir. 2001) (mandating that “a district court must continue to perform its gatekeeping role by ensuring that the actual testimony does not exceed the scope of the expert’s expertise” and holding that failure to do so is grounds for reversal on appeal).

ARGUMENT

This Court should exclude testimony from Dr. Buffington based on new evidence that severely undermines his credibility and reputation for truthfulness or untruthfulness. Furthermore, allowing Dr. Buffington to testify about pharmacological or anesthetic properties of midazolam or anesthesia monitoring would exceed the limits of his expertise. So too would permitting him to testify about orogastric or nasogastric tubing, pulmonary edema (or any other matter in the realm of medicine), or the medical-aid-in-dying matters addressed in his expert report. Likewise, permitting him to opine on legal matters is inappropriate and beyond the scope of his expertise, because he is not a lawyer.

The Sixth Circuit has upheld the district court’s exercise of discretion to exclude testimony as inadmissible when it does not meet the standards for admission of scientific evidence under *Daubert* and its progeny. *Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 248 (6th Cir. 2001). Likewise, other Circuits have found “no abuse of discretion in the limitation of the testimony of witnesses who, although considered experts in certain areas, were not well-versed in the particular discipline relevant to their testimony.” *See, e.g., Smith v. Rasmussen*, 249 F.3d 755, 759 (8th Cir. 2001) (listing cases). And lower

courts concluded that even being “an eminently well qualified and respected clinician and surgeon” is not enough to offer an expert opinion on areas that may be related to, but nonetheless are outside of, that physician’s expertise. *Avendt v. Covidien Inc.*, 314 F.R.D. 547, 562 (E.D. Mich. 2016).

Dr. Buffington, with a degree in pharmacy, may qualify as an expert for some matters under Federal Rule of Evidence 702. The real question, however, is “what is he an expert about?” *Wheeling Pittsburgh Steel Corp.*, 254 F.3d at 715. The field of pharmacy is simply not the same as the fields of pharmacology or anesthesiology. Pharmacology can be described as the study of the effect of drugs on living organisms, while pharmacy, on the other hand, can be described as the profession of reading prescription labels and dispensing drugs. *Dellinger v. Pfizer Inc.*, No. 5:03CV95, 2006 WL 2057654, at *8 n.16 (W.D.N.C. July 19, 2006); *Newton v. Roche Labs., Inc.*, 243 F. Supp. 2d 672, 677 n.1 (W.D. Tex. 2002). When a pharmacist like Dr. Buffington attempts to testify about the domain of pharmacology, such testimony is excluded. The same is true as to the other subject matters on which Dr. Buffington purports to provide an expert opinion.

I. New information obtained by Henness shows that Dr. Buffington made false statements to the IRS.

Tax records are admissible under Fed. R. Evid. 608(b) because they reflect on a witness’s credibility and reputation for truthfulness or untruthfulness. *Hunter v. Gen. Motors Corp.*, 149 F. App’x 368, 373 (6th Cir. 2005) (“Pursuant to the provisions of Federal Rule of Evidence 608(b), cross-

examination may delve into specific instances of conduct of the witness if probative and if that conduct concerns “the witness’ [sic] character for truthfulness or untruthfulness. . . . [T]he [tax] return did indeed reflect upon the plaintiff’s truthfulness and was, therefore, admissible at trial.”); *see also Howell v. Star-Kist Foods, Inc.*, 12 F.3d 212 (6th Cir. 1993) (finding tax returns were admissible to impeach witness’s credibility).

Since the last hearing in this consolidated case, tax records for the 501(c)(3) “charity” organization run by Dr. Buffington, the American Institute of Pharmaceutical Sciences, Inc., were obtained by the Office of the Federal Public Defender for the Southern District of Ohio.² They appear to show that Dr. Buffington obtained expedited consideration of his federal tax-exempt status under false pretenses.

In his CV, Dr. Buffington identifies himself as the “President & CEO” of the “American Institute of Pharmaceutical Sciences, Inc.” (ECF No. 1975-2, PageID 88096.) Despite that official-sounding title and an impressive-looking website, <http://www.aips.net>, Dr. Buffington testified in October 2017 that he runs this business out of the same address as all his other “businesses.” (Tr., ECF No. 1363, PageID 51475.) Public records show that these other “businesses” include various “expert” companies, as well as an entity entitled

² Tax returns and other filings of a 501(c)(3) organization are public records subject to requests under the federal Freedom of Information Act. *See* <https://www.irs.gov/charities-non-profits/exempt-organizations-public-disclosure-obtaining-copies-of-documents-from-irs>. These records were requested before the last hearing in October of 2017, but were not received until after the hearing.

“Conexus Health,” and what appears to be a now-defunct “Check Collection” business. (AIPS annual report, ECF No. 1315-10, PageID 48118; List of businesses registered to Dr. Buffington in Florida, ECF No. 1315-11, PageID 48119).

Dr. Buffington first applied for the tax-exempt status for AIPS in March of 2006. (Ex. 2 at 11.) At the time of the application, he was the sole member of the Initial Board of Directors, the Registered Agent, and the Incorporator. (Ex. 2 at 26.) Dr. Buffington asked for urgent consideration of his application, invoking disaster victims: “We are attempting to escalate the volume of services provided to indigent patients in [sic] State of Florida and victims of Hurricane Katrina to help meet their treatment needs through gifted medication products.” (Ex. 2 at 39.)

The IRS told Dr. Buffington that AIPS did not meet the criteria established to expedite the application, and that the IRS would only expedite an application if the organization was in danger of losing a pending grant. (Ex. 2 at 40.) Dr. Buffington obliged. He told the IRS on July 19, 2006 that AIPS is “preparing to receive a sponsorship grant in the amount of \$25,0000, from Dr. Matthew Bardin of Conexus Health. The deadline for eligibility for these funds is September 1, 2006.” (Ex. 2 at 41.) Dr. Buffington asked the IRS for “rapid review and approval . . . to help ensure that we do not miss this opportunity.” (*Id.*) He enclosed a letter from Conexus Health, signed by Dr. Matthew Bardin, addressed to Dr. Buffington, that stated Conexus “received your application and request for funding assistance” but that their “donation

process requires the organization to be deemed a 501c3 [sic] status.” (*Id.* at 42.) The letter warned that the donation would be available to AIPS only through September 1, 2006. (*Id.*) A month later, on the basis of that letter, the IRS agreed to expedite the request. (*Id.* at 43.)

But the exigent circumstances on which IRS based its approval were created by Dr. Buffington himself. Conexus Health is an organization *owned entirely by Dr. Buffington himself*. (Ex. 4.) The address listed on the letter to the IRS from Conexus—6403 S. Queensway Drive, Temple Terrace, FL 33617—is Matthew Bardin’s home address, and Conexus was never registered at that address. (See Articles of Organization, Ex. 4; 2018 Annual Report, Ex. 5.) Instead, Conexus Health has always been registered to the same address as Dr. Buffington’s other business and AIPS itself. (See Exs. 4 & 5; Ex. 2 at 25.) “Doctor” Matthew Bardin is another Pharm. D., Dr. Buffington’s next door neighbor, and a former part-time employee. (Exs. 6; 7; 8.) Dr. Bardin’s publically available LinkedIn page lists his occupation as “Clinical Science Liaison/ Consultant” for “Clinical Pharmacology Services, Inc./Conexus Health, LLC” from October 2004 to January 2007, during the time Dr. Buffington was applying for expedited status for AIPS. (Ex. 7.) Furthermore, a Mercer University Press Release from June 2005 boasts that “[c]urrently the president and CEO of Tampa-based Clinical Pharmacology Services, Dr. Buffington has developed two additional specialty consulting groups: Conexus Health, a medical education firm and Pharmacology Experts, which provided

expert testimony on pharmacology issues including medical malpractice, toxicology, criminal and product liability.” (Ex. 9. at 17.)

In other words, AIPS was never in danger of losing a pending grant. The money was simply being transferred from Dr. Buffington’s left hand to his right hand. During the time when the IRS’s attention was needed to process applications for non-profit organizations that were genuinely in danger of losing a pending grant or were truly trying to provide immediate assistance to disaster victims, Dr. Buffington asked the IRS to prioritize him. Dr. Buffington freely controlled Conexus’s bank account, so he was free to spend that money to help disaster victims if he chose. But instead, he prioritized obtaining a tax break.

It should be noted in connection with this transfer that moving income from a taxable for-profit corporation would entitled that corporation to take a tax deduction on the donated amount, while the charitable organization would pay no income but could still pay salaries (to the same individuals, even) and expenses such as rent (also at the same address).

At present time, Dr. Buffington admits that since 2015 AIPS has not had sponsors, donors, or members,³ and that no amounts were donated or granted

³ Buffington asserts in his Responses to a Rule 45 subpoena for production of documents that AIPS is not a 501(c)(6) organization. That is both correct and entirely irrelevant. Section 501(c)(6) of the Internal Revenue Code provides for the exemption of business leagues, chambers of commerce, real estate boards, boards of trade and professional football leagues. Nothing, however, prohibits 501(c)(3) organizations from charging membership fees. For example, the American Bar Association is a 501(c)(3) organization that charges membership fees. In fact, the AIPS Bylaws explicitly provide for membership: “Section 2.1. Membership. Membership in the corporation shall be open to all

to AIPS. (Ex. 1 at 8, Response #13.) He also admits that while AIPS's stated charitable purpose is to make distributions to qualifying 501(c)(3) organizations (Ex. 2 at 28), "there were no grants made to any organization or individual from 2015 to present." (Ex. 1 at 9, Response #14.) Likewise, copies of AIPS tax returns for 2012, 2013, and 2014 show that for those years, the amount granted or distributed was zero. (Ex. 3 at 4, 14, 24.) In other words, Dr. Buffington's charity does not fundraise, receive donations, make grants, or makes distributions to charitable organizations. It appears, however, to generate revenue through an income stream, and then pay rent and salaries, like any other business.

In sum, it appears that Dr. Buffington's "charitable" activities are highly suspect, including submitting paperwork to the IRS to obtain expedited grant of a tax-exempt status under a false pretense of exigent circumstances. Coupled with his previous filings of false information on his CV to this Court and others, these matters show Dr. Buffington's lack of credibility and illustrate his reputation for untruthfulness. As such, this Court should exclude any testimony from Dr. Buffington on Henness's motion for injunctive relief.

persons who meet the following criterion; MUST BE INTERESTED IN THE PURPOSES OF THE CORPORATION AND DESIROUS OF FUTHERING [sic] ITS GOALS." (Ex. 2 at 33). There are no members, however.

II. Under the *Daubert* standard, Dr. Buffington cannot be qualified as an expert in pharmacology, anesthesiology, the practice of medicine, or midazolam because he has no research experience specific to midazolam and he lacks training and experience in the fields of pharmacology or anesthesiology or general medicine.

Dr. Buffington filed a report opining on the pharmacological properties of midazolam, the creation of analgesia, the cause of pulmonary edema, medical-aid-in-dying matters and practices, and orogastric and nasogastric tube insertion and use, as well as offering factual and legal conclusions. (Report, ECF No. 1985.) These opinions exceed the scope of his expertise. Moreover, they are not based on sufficient data or facts. Furthermore, Dr. Buffington has consistently disregarded the mandatory disclosure requirements in Federal Rule of Civil Procedure 26(a), as explained at length in the motion to strike that Henness recently filed. (See ECF No. 1997.) The same arguments provided in that motion to support a request for sanctions under Rule 37 also justify excluding his testimony by way of this motion in limine.

For these reasons and as further explained below, Henness asks that the Court preclude Dr. Buffington from testifying or, at the very least, limit his testimony to the subject matter in which he is an expert, which is pharmacy. This Court should exclude any testimony from Dr. Buffington in the different fields of pharmacology, cardiology, anesthesiology, pulmonology, pathology, general medicine, medical-aid-in-dying, nasogastric or orogastric tubes, or any other field beyond pharmacy.

A. Dr. Buffington has not done any research related to any of the drugs at issue in this case; has not authored any publications in relevant areas; and has not induced general anesthesia or installed a nasogastric tube.

Dr. Buffington has never earned an M.D., a Ph.D., or any degree in pharmacology or anesthesiology. Motion at 5, *Arthur v. Dunn*, No. 11-cv-438, ECF 301 (M.D. Ala. Dec. 30, 2015) (citing Buffington Dep.). Dr. Buffington has never authored any papers that are specific to midazolam and never conducted any scientific studies that are specific to midazolam. (Tr., ECF 941, PageID 32028–29.) He reconfirmed that just yesterday, in his response to a Rule 45 subpoena. (See Exhibit 1, Responses to Requests ## at 2, 5–10.) In his responses to the subpoena, Dr. Buffington admitted that he has not “not designed, performed, or participated in a study of” midazolam, rocuronium bromide, potassium chloride, or secobarbital. (*Id.*) He has not “authored publications in peer-reviewed journals regarding midazolam, rocuronium bromide, potassium chloride, secobarbital, orogastric tubes, or nasogastric tubes.” (*Id.*, Response #10.) Dr. Buffington has never induced or maintained general anesthesia or used midazolam as an induction agent. (ECF 941, at PageID 32028–29; ECF No. 1363, PageID 51465.) He also has never actually put a feeding tube into a person; his experience with them is limited to advising on “which medications can be administered through feeding tubes.” (Ex. 1, Response #11.)

B. Dr. Buffington's description of his clinical experience with midazolam appears either illegal, fictional, or overstated.

Dr. Buffington has claimed expertise in the pharmacology of midazolam and the other subject matters based in no small part on having personally prescribed and administered midazolam. That is like if someone who drives a car attended three Formula 1 races, observed those races from the pits, and then, based on those experiences, claimed to have the expertise on par with the world's best racecar drivers. Moreover, it is questionable whether Dr. Buffington even has that limited experience he claims. Although he has claimed to have prescribed and administered midazolam, Dr. Buffington's responses change or become evasive each time he has been asked to clarify his experience with midazolam, further casting doubt on whatever limited experience he has with it (and also reinforcing his reputation for untruthfulness).

1. Dr. Buffington's testimony on prescribing and administering midazolam changes, even within the course of a single deposition.

In a deposition taken three years ago, in December 2015, Dr. Buffington testified at first that he never prescribed or administered midazolam or any other benzodiazepine. Buffington Dep. 8 (page 3 of 27), *Arthur v. Dunn*, No. 11-cv-438, ECF 301-1 (M.D. Ala. Dec. 30, 2015). Later in the same deposition, Buffington testified under oath that he did, in fact, prescribe and administer midazolam for "a patient." *Id.* at 133 (page 9 of 27).

When he testified before this Court in January of 2017, Dr. Buffington contradicted his prior testimony, this time saying that he prescribed

midazolam, but only after the deposition taken in 2015. (ECF 941, PageID 32025.) Dr. Buffington reiterated again that he never prescribed midazolam before the deposition in December 2015—contradicting his sworn statement in the Alabama case—but since then, he “think[s] probably three” is the number of times he prescribed and administered midazolam. (*Id.* at PageID 32026.)

But Dr. Buffington’s prescribing abilities appear, at the very least, to be overstated. Prescribing drugs, just like diagnosing and treating disease, is a function normally reserved exclusively to physicians, and prescribing controlled substances requires a DEA registration. (ECF 941, PageID 32069.) It is true that in Florida, pharmacists may order and dispense certain drugs without involving a physician. *See* Fl. Admin Code, Rule 64B8-36.003. These drugs, however, do not include controlled substances; they are limited to such items as acne products and medicated shampoo for treating head lice.⁴

2. Dr. Buffington was unable to produce any evidence that he actually prescribed and administered midazolam.

In another deposition, Dr. Buffington testified that he administered midazolam “[d]uring clinical research, during direct patient care procedures as part of various teams, in an emergency room scenario.” Buffington Dep. at 16, *Grayson v. Dunn*, No. 12-cv-00316, ECF No.145-4 (M.D. Ala. April 15, 2016).

⁴ See complete list here:
https://www.flrules.org/gateway/notice_Files.asp?ID=5002986.

And before this Court, Dr. Buffington also testified that he administered midazolam. (ECF 941, PageID 32025.)

Because midazolam is a controlled substance, Dr. Buffington or his practice or whatever “team” he was working under, was required to keep records related to its prescription, dispensing, and inventory. 21 C.F.R. §1304.04. And yet, when he was asked, in light of his previous testimony, to produce copies of those records, he was not able to. Dr. Buffington’s response was he has no such records in his possession, custody, or control. (Ex. 1, Response #1.) When asked about his role in these cases, Dr. Buffington answered “to provide specialty guidance on medications.” (*Id.*) Advising, however, is not the same as prescribing or administering the drug.

When asked about what NPI number⁵ he used when prescribing midazolam, Dr. Buffington responded he was not sure whether his “personal or practice NPI number would have been utilized.” (*Id.*) Centers for Medicaid and Medicare Services (CMS), where Dr. Buffington has been employed in some capacity for a number of years, has developed the National Plan and Provider Enumeration System (NPPES) to assign these unique identifiers. CMS issued several rules years ago. Among them was a rule in place since May 6, 2013, or

⁵ The National Provider Identifier (NPI) is a unique identification number for health care providers. Health care providers and all health plans and health care clearinghouses will use the NPIs in the administrative and financial transactions specified by Health Insurance Portability and Accountability Act (HIPAA). Think of it as a national bar number or a social security number: it is a unique, individual identifier number.

more than five years ago, requiring that all Prescription Drug Events must contain individual's NPI, not the practice NPI.⁶ Since Dr. Buffington works for CMS, he should be familiar with the regulations. And if he is prescribing midazolam, he should know to be using his personal NPI number, which he still has not disclosed. Accordingly, Dr. Buffington's claim to not know whether his "personal or practice NPI number would have been utilized," like his failure to produce documents showing his NPI number, is nonresponsive to the subpoena, as well as misleading and evasive—another example of his willingness to ignore the Federal Rules of Civil Procedure.

Additionally, and in light of Dr. Buffington's claim to expertise related to midazolam based on having administered or prescribed it, Henness subpoenaed Dr. Buffington and asked him to provide documents related to each of the three scenarios in which he testified he administered midazolam: "[d]uring clinical research, during direct patient care procedures as part of various teams, in an emergency room scenario." Buffington Dep. at 16, *Grayson v. Dunn*, No. 12-cv-00316, ECF No.145-4 (M.D. Ala. April 15, 2016). And yet, Dr. Buffington was unable to provide a single responsive document for any of the three scenarios.

⁶ See CMS, Regulation and Guidance, <https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/NationalProvIdentStand/Downloads/NPI-Requirements-for-Prescribers.pdf> (last accessed Nov. 21, 2018).

C. Dr. Buffington lacks education and training in pharmacology, anesthesiology, or consciousness.

In addition to the questions raised above, Dr. Buffington made numerous misleading presentations to this and other federal courts regarding his education. For instance, Dr. Buffington represented to this Court in December of 2016, by filing his CV, that he completed a Clinical Pharmacokinetics Residency. (ECF No. 870-1, PageID 28177.) See illustration 1.

EDUCATION:	
Postgraduate	Emory University Hospital, Atlanta, GA
	Clinical Research Fellowship 07/1988 – 06/1989
	Clinical Pharmacokinetics Residency 07/1987 – 06/1988

Illustration 1. (ECF No. 870-1, PageID 28177.) Similarly, in interrogatory responses filed with this Court, Defendants also insisted that Dr. Buffington completed a “Clinical Pharmacokinetics Residency” at Emory University Hospital. (ECF No. 1285-1, PageID 46884.)

And yet, during cross-examination in October 2017, Dr. Buffington admitted that his residency was a “General Clinical Residency” or “General Pharmacy Residency.” (ECF No. 1363, PageID 51467–68.)

Now, his new submission to the Court has changed; it now describes his residency as a “Pharmacy Practice Residence.” (ECF No. 1975-2, PageID 88095.) Three different representations on three different occasions for the same entry on his CV calls into question Dr. Buffington’s reputation for truthfulness, and further undermines any claim that that he can offer expertise on matters of pharmacology or things beyond pharmacy.

But that is not all. Dr. Buffington has also changed his fellowship description from “Clinical Research Fellowship” to “Clinical Pharmacology Fellowship.” *Id.* Available copies of his CV show that Dr. Buffington has been reporting his fellowship as “Clinical Research Fellowship going back to at least 1991. (Ex. 9 at 10.) He changed “research” to “pharmacology” in his fellowship description after the October 2017 hearing in Ohio before this Court, when the only other educational link to “pharmacology” in his residency description was shown to be untrue.

Just like with other requests for proof of his experience, when Dr. Buffington was asked to produce documents that demonstrate he completed this fellowship, Dr. Buffington was unable to comply. Instead, he appended a letter to his report from the current Assistant Director of Clinical and Educational Services at Emory Healthcare, that incorporates another letter from Dr. Buffington’s mentor. (ECF No. 1312-1, PageID 47569). But those two letters do not even agree on the names of the programs he completed. One letter states he completed “PGY-1 Pharmacy Practice Residency.” The other, “Clinical Pharmacy Practice.” One letter states he completed a “Clinical Pharmacotherapy Fellowship.” The other, “Clinical Pharmacology Fellowship.” *See id.* Neither letter, moreover, is an official school record, diploma, degree, or certificate.

After being questioned about other discrepancies on his resume regarding his employment dates and titles during the October 2017 hearing in this consolidated case, Dr. Buffington promised he would update it: “When I

get back from this trip, I have got a conference room of documents laid out to do this.” (ECF No. 1363, PageID 51469.) But he didn’t. Five months later, in March of 2018, Dr. Buffington submitted his CV to the United States District Court for the Middle District of Alabama.⁷ The CV still misrepresented to a federal court that he completed a “Clinical Pharmacokinetics Residency.” It also misrepresented his employment status at various entities he acknowledged during his testimony before this Court were wrong. (ECF No. 1363, PageID 51469, 51471–72.)

Finally, it should be noted that Dr. Buffington’s CV does not misrepresent his experience with anesthesiology, consciousness, sensation, feeding tubes, pulmonary edema, or the law; there is nothing on his CV at all about those topics.

D. Dr. Buffington’s work and teaching experience do not qualify him as an expert in this case.

Dr. Buffington’s work experience appears to be as difficult to verify as his education credentials. On the basis of what could be uncovered, however, his work experience is insufficient to qualify him as an expert for the purposes of the upcoming hearing.

⁷ State’s Response Ex. A, ECF No. 391-1, No. 12-cv-00316, *In Re: Alabama Lethal Injection Protocol Litigation* (M.D. Ala. Mar. 27, 2018).

**1. “American Institute of Pharmaceutical Sciences, Inc”
does not do pharmaceutical research.**

Regardless of what else AIPS does as a “charity,” Dr. Buffington’s IRS filings make clear that it does not do pharmaceutical research. “The type and nature of our clinical research is *not* that which is typically involved with the commercial development of a specific medication. Our research could involve trial designs such as **surveys of healthcare professionals, patients, government healthcare agencies** and observational research that focuses on healthcare process and outcomes. For example: incidence of adverse drug reactions in nursing homes, patient awareness of potential side effects, rates of treatment compliance with HIV medication regimens, etc.” (Ex. 2 at 48.) (emphasis added).

In response to another question from the IRS, Dr. Buffington specifically stated that he does not test medications: “Clinical research does not solely mean ‘testing of medications.’ Rather, it means the study of medications in humans. **Clinical research can evaluate healthcare practitioner, patient, or healthcare facilities processes, policies, knowledge of healthcare topics.** Clinical research, meaning evaluation of healthcare issues can provide statistical data on the incidence of adverse drug reactions, positive health outcomes, compliance with treatment guidelines, and other factors that involve process or policy development.” (*Id.* at 48.) (emphasis added).

In another response, Dr. Buffington again unequivocally disavowed actually studying or testing drugs: “We are not planning on providing ‘drug testing’ studies While our entire focus is on the appropriate use of

medications, which by nature are pharmaceuticals, one of our organizational goals is to create research projects that assess, document and **evaluate healthcare process and policies** that impact the decisions and patterns of medication use in order to improve healthcare and prescribing practice.” (*Id.* at 49.) (emphasis added).

If Dr. Buffington’s statements to the IRS are truthful, the research he conducted at AIPS is conducted using surveys and statistical analysis and is aimed at policy changes. It is not, as he repeatedly disavowed, “research” or “testing” in the way that Henness’s experts conduct research. But AIPS was not involved even in the kind of policy research related to the drugs at issue here. In his subpoena response, Dr. Buffington admits that AIPS has conducted no research related to midazolam, rocuronium bromide, potassium chloride, or secobarbital. (*See generally* Ex. 1, Responses.) Therefore, he cannot be qualified as an expert on the basis of his involvement with AIPS.

2. Dr. Buffington is not qualified on the basis of his involvement with professional organizations.

Dr. Buffington represented to the Court by way of his CV that he is involved in various professional organizations. (ECF No. 1975-2, PageID 88098.) In his report, Dr. Buffington also emphasized that he is “active” in “numerous local, state, and national professional associations, including the American Medical Association (AMA) . . . [and the] American College of Clinical Pharmacy (ACCP).” (ECF No. 1985, PageID 91019.) In part on the basis of that involvement with professional organizations, the State of Alabama sought his

admission as an expert witness in pharmacology: “Dr. Buffington is also a member of American College of Clinical Pharmacology.”⁸

In response to a Rule 45 subpoena from Henness, ACCP quickly located Dr. Buffington’s application. (Ex. 9.) But ACCP failed to uncover any evidence of Dr. Buffington’s committee participation, any registration at the ACCP Annual meeting, which would have precluded him from participating as “faculty, a poster presenter or an attendee,” or any participation in online courses. (*Id.*) And simply being a member of ACCP, in and of itself, conveys no imprimatur of expertise in pharmacology; anyone with a Bachelor’s Degree in *any* healthcare field (nursing, hospital management, dermatology) and interest in pharmacology can join ACCP. (*Id.* at 4.)

Dr. Buffington also insists that he is a current member of the American Medical Association (AMA) and lists a number of committees in which he is currently involved. (ECF No. 1975-2, PageID 88098.) But that appears to be questionable too, because an effort to find his membership in the AMA revealed no current membership for a Daniel E. Buffington. (See Ex. 10 (search results identifying only Daniel Joseph Buffington, M.D., of the University of Arizona College of Medicine).)

Therefore, it cannot reasonably be said that Dr. Buffington qualifies as an expert in pharmacology or any other subject matter beyond pharmacy on the basis of his mere affiliation with professional organizations.

⁸ State’s Response, ECF No. 391, No. 12-cv-00316, *In Re: Alabama Lethal Injection Protocol Litigation* (M.D. Ala. Mar. 27, 2018).

3. Including the word “pharmacology” in the name of his business does not make Dr. Buffington an expert in pharmacology or any other subject matter beyond pharmacy.

Dr. Buffington lists “Clinical Pharmacology Services” on his CV. But including the word “pharmacology” in the name of his business does not make Dr. Buffington an expert in pharmacology. He previously testified that this business, Clinical Pharmacology Services, “provide[s] a consult service, again, for patients. We classify that as medication therapy management, where patients are either referred or self-referred to our practice to have their medications reviewed, to look for and identify any problem areas or opportunities for improving or optimizing their drug regimen.” Buffington Dep. 9:5-11, *Philadelphia Life Ins. Co. v. Buckles*, No. 7-cv-1743, ECF No. 75-6, PageID 1359 (M.D. Fla. Dec. 19, 2008). Another service his business provides is “the drug information service, those are questions that come in from outside parties, could be patients, healthcare facilities or entities, and/or managed care organizations doing drug policy development.” *Id.*

On Dr. Buffington’s website, prospective clients are told that his company provides “comprehensive reviews of your prescription and non-prescription medications, and work closely with your healthcare providers to personalize your therapy.”⁹ Reviewing prescriptions, however, is very different from induction of anesthesia or even administration of those medications. It

⁹ Clinical Pharmacology Services, https://www.cpshealth.com/site/services_patientcare, last accessed Nov. 21, 2018.

does not appear that the company actually dispenses any drugs or has them on the premises: “We do not serve as a traditional ‘dispensing’ pharmacy. Therefore, we do not maintain a routine medication inventory.”¹⁰

Again, none of this has any relevancy to the study of pharmacology, anesthesiology, medicine in general, or any of the other subject areas in which Dr. Buffington claims expertise beyond pharmacy.

4. Dr. Buffington’s teaching experience does not provide for a sufficient link to pharmacology, anesthesiology, or any other subject matter beyond pharmacy.

Dr. Buffington’s teaching experience does not provide for a sufficient link to pharmacology. In a 2008 deposition, in response to the question “Can you briefly describe for me the courses that you teach,” Dr. Buffington responded “The areas that we focus on [are] . . . clinical pharmacology, so that’s anything encompassing the prescription management, the prescribing skills. It also includes drug development and research and also includes drug policy development.” Buffington Dep. 11:8-15, *Philadelphia Life Ins. Co. v. Buckles*, No. 7-cv-1743, ECF No. 75-6, PageID 1359 (M.D. Fla. Dec. 19, 2008). But this teaching experience, despite Dr. Buffington’s use of the term “clinical pharmacology,” is consistent with the study of **pharmacy**, which is about “reading prescription labels and dispersing drugs.” *Dellinger v. Pfizer Inc.*, No. 5:03CV95, 2006 WL 2057654, at *8 n.16 (W.D.N.C. July 19, 2006).

¹⁰ Clinical Pharmacology Services, <https://www.cpshealth.com/site/faq>, last accessed Nov. 21, 2018.

Pharmacology, on the other hand, is the study of the effect of drugs on living organisms. *Id.* That is not within Dr. Buffington's description of his courses.

E. Dr. Buffington tends to overstate his level of involvement and practical experience.

In the past, Dr. Buffington also claimed that as a licensed pharmacist in Florida, he is permitted to diagnose and treat cardiovascular disease.

Buffington Dep. 132–33, 136 (pages 9, 10 of 27), *Arthur v. Dunn*, No. 11-cv-438, ECF 301 (M.D. Ala. Dec. 30, 2015). Dr. Buffington testified that “in the Florida law [there] is something referred to as collaborative drug therapy management and those are practice parameters for pharmacists to diagnose, treat and manage drug therapy, which includes prescription, the initiation, the modification and the termination.” *Id.* at 136.

But that is not what Florida law actually says. Standards of practice for Drug Therapy Management allow a pharmacist to perform tasks beyond the pharmacist's typical scope of practice, *but only pursuant to a plan written by a physician*. Fla. Admin. Code. 64B16-27.830 (2013) (“The Prescriber Care Plan shall be written by a physician . . . [and] shall specify the conditions under which a pharmacist shall order laboratory tests, interpret laboratory values ordered for a patient, execute drug therapy orders for a patient, and notify the physician.”)

Thus, Dr. Buffington's alleged ability to treat and diagnose cardiovascular disease would far exceed his level of competence and what he is allowed to do under Florida law. Nonetheless, in his report filed with a federal

district court in Arkansas, he opined on the probability of ischemic cardiac damage and acute cardiac events. (Report at 9 ¶ 14, *McGehee v. Hutchison*, No. 17-cv-179 (D. Ark. Apr. 14, 2017), ECF No. 28-4. It is not clear if Dr. Buffington now bases his alleged expertise on pulmonary edema on similar reasons. But if so, those reasons are insufficient to qualify him as an expert in that medical topic.

F. Conclusion

In sum, under the *Daubert* standard and Rule 702, Dr. Buffington cannot be qualified as an expert in pharmacology, anesthesiology, the practice of medicine, or midazolam because he lacks specific training, education, and experience in those areas. He cannot opine on pharmacological properties of midazolam or induction of anesthesia, nor can he testify about or opine on, diagnose, or suggest causes of medical conditions, such as pulmonary edema.

III. Opinions outside of a pharmacist's area of competence must be excluded.

In addition to the roadblock presented by the *Daubert* standard, Dr. Buffington also faces a similar roadblock in the law that specifically precludes a pharmacist from offering opinions outside a pharmacist's areas of competence and expertise. Dr. Buffington's expert report (ECF No. 1985) offers numerous opinions that are outside the scope of his area of competence. He also asserts expertise in a wide range of specialty far beyond pharmacy. (See, e.g., ECF No. 1985, PageID 91018.) Those opinions should be struck from his

report, his purported areas of expertise beyond pharmacy should be struck, and any testimony on those matters should be excluded.

A. Courts exclude the testimony of pharmacists when they attempt to render an opinion outside of their area of expertise.

Courts exclude the testimony of pharmacists when they attempt to render an opinion regarding the effects of drugs on living organisms, because such opinion ventures into the realm of pharmacology, and, therefore, exceeds the scope of a pharmacist's expertise. In *Newton v. Roche Labs.*, 243 F. Supp. 2d 672, 677 (W.D. Tex. 2002), the district court precluded a pharmacist with a Pharm.D. degree from testifying about the pharmacological effects of a drug. The court held that a pharmacist, even one who "holds himself out" as a pharmacologist like Dr. Buffington does, lacks qualifications to render an opinion on the pharmacological effects of the drug. *Id.*

Like Dr. Buffington, the proffered expert in *Newton* never earned an M.D., a Ph.D., or any degree in pharmacology. *Id.* Like Dr. Buffington, that expert's claim to the title of "doctor" was based solely upon the completion of a "Pharm. D" program. Like Dr. Buffington, the *Newton* expert never performed even basic bench or clinical research on the drug at issue. *Id.* at 678. Like Dr. Buffington, the *Newton* expert based his opinion "solely on an incomplete review of existing literature." *Id.* The court pointed out that "an individual's 'review of literature' in an area outside his field does 'not make him any more qualified to testify as an expert . . . than a lay person who read the same articles.'" *Id.* (quoting *United States v. Paul*, 175 F.3d 906, 912 (11th Cir.

1999)). The *Newton* court held that the party could not present the pharmacist as an expert on the effects of the specific drug at issue on the human body; even presenting him as an expert pharmacologist “[q]uite frankly, the Court [found] . . . to be an extremely bold stretch.” *Id.* at 679.

Another district court followed suit, and also prevented a pharmacist from testifying about the effects of a drug on a human body. *Dellinger v. Pfizer Inc.*, No. 5:03CV95, 2006 WL 2057654, at *8 (W.D.N.C. July 19, 2006).

“Without a degree in pharmacology, [pharmacist] Keays is not qualified to render a relevant or reliable pharmacological opinion regarding the effects of [a drug].” *Id.* The court also emphasized that, in addition to a lack of professional training in pharmacology, the would-be expert never performed independent research on the pharmacologic design, efficacy or mechanism of the drugs at issue. *Id.* Neither did Dr. Buffington in this case. Like Dr. Buffington’s opinion, the proposed expert’s opinion in *Dellinger* was not based on his own, preexisting, independent research. *Id.* at 10. For these reasons, the *Dellinger* court held that the opinion of a pharmacist is inadmissible on matters of pharmacology.

Similarly, the Fourth Circuit held that the district court did not abuse its discretion in excluding testimony, in its entirety, of a retired pharmacist and toxicologist because he was neither a pharmacologist nor a medical doctor. *Wehling v. Sandoz Pharm. Corp.*, 1998 WL 546097, at *4 (4th Cir. 1998). Like Dr. Buffington, the pharmacist in *Wehling* developed a purported expertise in drug and alcohol testing, particularly in the context of automobile accidents.

Id. The trial court concluded (and the court of appeals affirmed) that this experience was not relevant, and the pharmacist was not qualified to testify about the effects of the drug in question on the brain or drug interactions occurring in the human body. *Id.* Like other courts, the Fourth Circuit also held that “[w]ithout prior training, education, or experience in the field, [the proposed expert’s] review of the literature, after he was retained as an expert witness in this suit, was insufficient to qualify him as an expert on the issues in dispute.” *Id.*

Finally, the court in *Devito v. Smithkline Beecham Corp.*, No. 02-CV-0745NPM, 2004 WL 3691343, at *7 (N.D.N.Y. Nov. 29, 2004), similarly held that a pharmacist cannot opine to a “reasonable pharmacological certainty” about effects of a drug. And like the other courts, the *Devito* court eschewed “litigation-drive[n] expertise” obtained by selective review of the relevant literature. *Id.* The court precluded the testimony of the proposed “expert.” *Id.* at *12.

B. Dr. Buffington’s opinions outside of the area of his expertise (pharmacy) should be struck from his expert report and any associated testimony excluded.

Eschewing litigation-driven expertise, several of Dr. Buffington’s opinions should be struck and any testimony on those topics excluded because they are far too attenuated with his education and training, even on their face.

1. Opinions about pharmacology should be struck and associated testimony excluded.

Dr. Buffington's testimony on the pharmacological effects of midazolam greatly exceeds Dr. Buffington's field of expertise as a pharmacist, since it goes well beyond questions about reading prescription labels and dispensing drugs. Dr. Buffington's teaching, education, and experience have little to do with the study of the effects of drugs in the human body. His credentials appear to be mutable, unverifiable or overinflated, and inaccurate at best, and his authority to diagnose and treat patients or prescribe and administer drugs, especially controlled substances, is—at a minimum—inflated.¹¹

Dr. Buffington may have reviewed some literature on midazolam after he was hired as a litigation expert, but that is the quintessential “litigation-driven expertise” that courts have consistently eschewed. In his previous report in this consolidated case, Dr. Buffington admitted that his opinions “are based on [his] review of the scientific and medical literature to date.” (Report ¶ 13, ECF No. 1312-1, PageID 47552.) This time, he simply cites studies on medical-aid-in-dying, pulmonary edema, and nasogastric tubes. (*See, e.g.*, ECF No. 1985, n. 4, 5, 11.) But whatever knowledge Dr. Buffington derived from reading studies after he has been retained to testify is not sufficient to render him an expert. “Without prior training, education, or experience in the field, [the

¹¹ Henness has numerous subpoenas outstanding to various organizations with which Dr. Buffington claims to be involved. On the basis of prior discoveries of significant discrepancies between Dr. Buffington's CV and reality, Henness expects to receive even more impeaching evidence about Dr. Buffington's credibility and reputation for truthfulness before the hearing.

proposed expert's] review of the literature, after he was retained as an expert witness in this suit, was insufficient to qualify him as an expert on the issues in dispute.” *Wehling v. Sandoz Pharm. Corp.*, 1998 WL 546097, at *4 (4th Cir. 1998).

It should be noted that Dr. Buffington deliberately created a business to be a professional expert witness: “Currently the president and CEO of Tampa-based Clinical Pharmacology Services, Dr. Buffington has developed two additional specialty consulting groups: Conexus Health, a medical education firm and Pharmacology Experts, which provided expert testimony on pharmacology issues including medical malpractice, toxicology, criminal and product liability.” (Ex. 9 at 17.)

Dr. Buffington lacks that requisite prior experience and is testifying as a professional gun-for-hire, not a genuine expert in the relevant field of science, in contrast with Henness’s expert witnesses. His opinions on pharmacological effects of midazolam, anesthesia, consciousness, and feeding tubes are outside of his competence and must be excluded.

2. Opinions about pulmonary edema should be struck and associated testimony excluded.

In paragraph 20 of his expert report, Dr. Buffington opines on matters concerning the genesis of pulmonary edema. He misinterprets or mischaracterizes the studies to which in cites in that paragraph. But more important, a pharmacist is not qualified to opine on medical causation. See, e.g., *Kelly v. Ford*, 543 S.W.3d 383, 387 n.3 (Tex. App. 2018). And yet, that is precisely what Dr. Buffington purports to do when he opines on whether

midazolam would cause pulmonary edema throughout paragraph 20. (ECF No. 1985, PageID 91023.) Those opinions should be struck and any such testimony excluded. He does the same in paragraph 24, and the opinions in that paragraph struck and any such testimony excluded.

3. Opinions that amount to legal fact-finding or that touch on medical-aid-in-dying subject matter should be struck and associated testimony excluded.

In paragraph 21 of his report, Dr. Buffington posits statements that opine not on matters of pharmacy but on whether there is sufficient evidence, in his view, to reach a particular legal conclusion: “The inaccuracy of his statement is that there has been no evidence to date that an inmate would be expected to experience severe pain or suffering associated with a three-drug LIP that includes midazolam.” (*See id.* at PageID 91024). That legal conclusion should be struck and any such testimony excluded.

In the same paragraph, Dr. Buffington also offers opinions about risk factors in the medical aid in dying context. But he offers no evidence to suggest he has any meaningful experience in that field, so those opinions should also be struck and any such testimony excluded.

4. Opinions regarding the insertion of a nasogastric or orogastric tube should be struck and excluded.

In paragraphs 25 and 26, Dr. Buffington provides opinions related to insertion of nasogastric and orogastric tubes. (*See id.* at PageID 91025–26.) But he is a pharmacist, not a medical care provider (or even a paramedic) who would have actual experience and training to insert such tubes. Consequently, those opinions should also be struck and any such testimony excluded.

IV. ANY expert testimony from Dr. Buffington should be excluded because he failed to provide the required disclosures under Rule 26(a).

In addition to the bases set out above, any testimony from Dr. Buffington at all should be excluded because he has consistently failed to comply with Rule 26(a)'s requirements for an expert witness's disclosures. (See ECF No. 1997.) For the reasons articulated in Henness's motion to strike Dr. Buffington's expert report as non-compliant with Rule 26 (*id.*), incorporated here by reference, Dr. Buffington's testimony on Henness's motion should be excluded as well. That is only further reconfirmed by Defendants' further non-compliant responses filed earlier today. (See ECF No. 2020 & attached exhibits.)

CONCLUSION

Rule 702 imposes on this Court a “gatekeeping role” to prevent the introduction of purported expert testimony that is insufficiently reliable. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589, 597 (1993). Dr. Buffington’s opinions are inherently unreliable because 1) he is not qualified on the basis of his education, training, or experience; 2) he is not a credible witness and has demonstrated a reputation for untruthfulness; and 3) he purports to offer expert testimony on a wide range of subjects for which he has no basis for expertise at all.

For all of the reasons identified herein, Henness asks the Court to strike Dr. Buffington’s report and preclude him from testifying. Should the Court permit Dr. Buffington to testify at all, his testimony must be solely confined to his area of expertise; the practice of pharmacy, which involves the reading and filling of prescriptions and dispensing medications, not the effects of drugs on the body or any other matters including general medicine.

Respectfully submitted this 21st day of November, 2018.

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by

and

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Certificate of Service

I hereby certify that on November 21, 2018, I electronically filed the foregoing **Motion in Limine to Exclude Testimony of Daniel Buffington** with the Clerk of the United States District Court for the Southern District of Ohio using the CM/ECF system, which will send notification of such filing to all parties by operation of the Court's electronic filing system.

/s/ Allen L. Bohnert
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